3510-16-P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO-P-2019-0009]

RIN 0651-AD33

Small Entity Government Use License Exception

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Final rule.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) is amending the rules of practice in patent cases to clarify and expand exceptions to the rule pertaining to government use licenses and their effect on small entity status for purposes of paying reduced patent fees. The rule change is designed to support independent inventors, small business concerns, and nonprofit organizations in filing patent applications and to encourage collaboration with the Federal Government by expanding the opportunities to qualify for the small entity patent fees discount for inventions made during the course of federally funded or federally supported research.

DATES: *Effective date:* This final rule is effective on January 20, 2021.

FOR FURTHER INFORMATION CONTACT: James Engel, Senior Legal Advisor, Office of Patent Legal Administration, by phone at 571-272-7725, or by email at James.Engel@uspto.gov; or Marina Lamm, Patent Attorney, Office of Policy and International Affairs, by phone at 571-272-5905, or by email at Marina.Lamm@uspto.gov.

SUPPLEMENTARY INFORMATION: The USPTO is amending the rules of practice in patent cases at 37 CFR 1.27 to clarify and expand exceptions to the rule pertaining to government use licenses and their effect on small entity status for purposes of paying reduced patent fees, so as to support independent inventors, small business concerns, and nonprofit organizations in filing patent applications. The government use license exceptions in this rulemaking are the only exceptions to the general rule that every party holding rights to an invention must qualify as a small entity under 37 CFR 1.27 in order for small entity status to be claimed in a patent application.

The first exception—in section 1.27(a)(4)(i)—covers a government use license that a Federal employee-inventor is obligated to grant if he/she is allowed to retain title to the workplace invention pursuant to a rights determination under Executive Order (E.O.) 10096. The Office is amending the regulations to specify that this exception applies to the use license reserved to the Federal Government when a Federal employee, including an employee of a Federal laboratory, is allowed, under 15 U.S.C. 3710d(a), to retain title to the workplace invention. The Office is also expanding the exception to cover a government use license to a Federal agency arising from an inventor's retention of rights under 35 U.S.C. 202(d), when the inventor is the employee of a small business or nonprofit organization contractor performing research under a funding agreement with the Federal agency, and the government use license is equivalent to that specified in 35 U.S.C. 202(c)(4). Retention of rights by the inventor under 35 U.S.C. 202(d)

becomes possible when the contractor performing research under a Federal funding agreement does not elect to retain title to the invention, and the Federal agency is not interested in pursuing the patent rights either. Provided the Federal agency receives no more than the government use license and there is no other interest in the invention held by a party not qualifying as a small entity, the inventor who otherwise qualifies for small entity status is not prohibited from claiming small entity status as a result of retaining rights under 35 U.S.C. 202(d), to his or her invention.

The second exception—in section 1.27(a)(4)(ii)—provides that a small business concern or nonprofit organization, which otherwise qualifies as a small entity for purposes of paying reduced patent fees under 37 CFR 1.27, is not disqualified as a small entity because of a license to a Federal agency pursuant to 35 U.S.C. 202(c)(4). Section 202(c)(4) reserves to the Federal agency a government use license in any invention made by a "contractor" (e.g., small business concern or nonprofit organization) pursuant to activities under a "funding agreement," as those terms are defined in 35 U.S.C. 201(b) and (c), when the contractor elects to retain title to a subject invention. It was brought to the USPTO's attention that much uncertainty existed as to whether the paragraph (a)(4)(ii) exception applies in cases in which there is a Federal employee co-inventor. In response, this rule amends 37 CFR 1.27(a)(4)(ii) to refer to 35 U.S.C. 202(e)(1), which permits the Federal agency, in the case of a Federal employee co-inventor, to "license or assign whatever rights it may acquire in the subject invention to the nonprofit organization, small business firm, or non-Federal inventor … " Section 1.27(a)(4)(ii) is being clarified to explicitly state that when the Federal agency takes action under 35 U.S.C. 202(e)(1) to place all ownership rights with the contractor, leaving to the Federal agency only the government use license under 35 U.S.C. 202(c)(4), the exception under section 1.27(a)(4)(ii) still applies. This is appropriate, given that a small entity contractor joint owner of a patent has the right to "make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into

the United States, without the consent of and without accounting to the other owners" pursuant to 35 U.S.C. 262. Furthermore, Federal agency action to assign rights under 35 U.S.C. 202(e)(1) leaves to the Federal agency only the government use license, which is what the Federal agency would have acquired had there been no Federal employee co-inventor.

Cooperative research and development agreements (CRADAs) are another important tool to promote collaboration between Federal agencies and non-Federal parties, including those qualified as small entities. In support of research consistent with the mission of the Federal "laboratory" as that term is defined in 15 U.S.C. 3710a(d)(2), under CRADAs, the Government, through its laboratories, provides personnel, facilities, equipment, intellectual property, or other resources, except for funds to non-Federal parties, and the non-Federal parties provide their own resources, which may include funds, for the collaborative activities. A CRADA may stipulate that the collaborating party assumes responsibility for the filing and prosecution of a patent application directed to a joint invention made under the CRADA and retains title to such invention, with the goal of achieving the practical application of technology advancements through commercialization. The Federal law providing for CRADAs (15 U.S.C. 3710a) reserves an obligatory government use license in exchange for ownership rights retained by the collaborating party much the same way as discussed above with respect to Federal funding agreements and Government employee inventions. It was reported that some small businesses and nonprofit organizations were hesitant to enter into CRADAs with the Federal Government because, prior to this rulemaking, they would have automatically lost their small entity status and would have to pay full patent fees (undiscounted patent fees) as a result of granting the government use license or the Government's interest in a joint invention. In response to these concerns, and in order to encourage small business and nonprofit organization collaborating parties to take the initiative for filing and prosecuting patent applications for their inventions at no expense to the Government, this rule expands the exceptions in 37 CFR 1.27(a)(4) by adding

a new section, 1.27(a)(4)(iii), that covers government use licenses that arise in certain situations when an otherwise qualifying small entity retains ownership rights to its invention made under a CRADA. This expansion of the government use license exception, as it pertains to federally supported research, is consistent with the President's "Return on Investment Initiative," as it applies to transferring technology to the private sector that originated from federally funded research or non-funded research performed at a Federal agency laboratory. *See* NIST Special Publication 1234 titled "Return on Investment Initiative for Unleashing American Innovation" (April 2019).

Background: The Patent and Trademark Law Amendments Act, Pub. L. 96-517, 94 Stat. 3015 (Dec. 12, 1980)—commonly referred to as the Bayh-Dole Act—added chapter 18 (sections 200 et seq.) to 35 U.S.C. to "encourage maximum participation … in federally supported research and development efforts" (35 U.S.C. 200) by giving small businesses and nonprofit organizations the ability to elect to retain title to their inventions made under Federal funding agreements. For more than 35 years prior to this rulemaking, the USPTO has provided the exception—now at 37 CFR 1.27(a)(4)(ii)—for Bayh-Dole Act government use licenses under 35 U.S.C. 202(c)(4). Similar to the Bayh-Dole Act, the Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. 96-480, 94 Stat. 2311 (Oct. 21, 1980), as amended by the Federal Technology Transfer Act of 1986, Pub. L. 99-502, 100 Stat. 1785 (Oct. 20, 1986) (FTTA), seeks to promote development and utilization of technologies made with Federal support. Unlike the Bayh-Dole Act, whereby support is in the form of Federal funding, the FTTA, among other things, authorized CRADAs as the basis for research collaboration between Federal agencies and private sector businesses and organizations, including small business concerns and nonprofit organizations. Unlike 35 U.S.C. 202(c)(4) government use licenses, the patent rules did not previously provide an exception for government use licenses reserved to the Government under CRADAs in exchange for the small business concern or nonprofit organization's retention of

ownership rights to its invention made during research at the partnering Federal laboratory. In response to feedback from Federal agencies concerning the importance of the small entity discount to promote collaboration with small businesses and nonprofit organizations and technology transfer efforts of Federal agencies and laboratories, the USPTO is revising the patent rules to add a government use license exception that applies to small entities that make an invention under a CRADA with a Federal laboratory.

The statutory provisions for CRADAs, similar to those for Federal funding agreements under the Bayh-Dole Act, reserve to the Federal Government use licenses for inventions made under a CRADA. 35 U.S.C. 202(c)(4), which provides the Bayh-Dole Act version of the government use license, and the CRADA government use license found in 15 U.S.C. 3710a(b)(2) and 3710a(b)(3)(D), are practically identical in scope. As set forth in 35 U.S.C. 202(c)(4):

> With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.

Under the Bayh-Dole Act provisions, the awardee of Federal funding is called a "contractor." Under the CRADA provisions of the FTTA, the term used for a participating non-Federal party is "collaborating party." In addition, the CRADA government use license refers to "the laboratory" or "the Government" as the recipient, rather than "the Federal agency."

The patent rules continue to provide a government use license exception for licenses arising under 35 U.S.C. 202(c)(4). Being added are exceptions for government use licenses that may arise under a CRADA pursuant to 15 U.S.C. 3710a(b)(2) or 3710a(b)(3)(D). Section 3710a(b)(2)

concerns the use license reserved to the Government for an invention made solely by employees of the collaborating party, and section 3710a(b)(3)(D) concerns the use license reserved to the Government when the laboratory waives ownership rights to a subject invention made by the collaborating party or an employee of the collaborating party. This rulemaking adds to 37 CFR 1.27 a new paragraph (a)(4)(iii) providing an additional exception for government use licenses under 15 U.S.C. 3710a(b)(2) and 3710a(b)(3)(D) for inventions made by small entities under a CRADA with a Federal laboratory.

Further, with respect to the exception for the government use license under 35 U.S.C. 202(c)(4) as it existed prior to this rulemaking, it was reported to the USPTO that small business firms and nonprofit organizations had become increasingly concerned that contributions of Federal employees in joint inventions could eliminate their entitlement to small entity status. In response, the section 1.27(a)(4)(ii) exception—the so-called "federal licensing safe harbor provision"—is amended to clarify in a new paragraph (B) that the exception applies when there is a Federal employee co-inventor, and action is taken under 35 U.S.C. 202(e)(1) by the Federal agency. Under section 202(e)(1), the funding Federal agency may license or assign whatever rights the Federal agency acquired in the subject invention, made by the contractor with a Federal employee co-inventor, to the contractor, in accordance with the provisions of 35 U.S.C. chapter 18, which include a government use license. The section 1.27(a)(4)(ii) exception is amended to explicitly apply, under new paragraph (B), to such situations. When an employee of the small entity contractor and an employee of the Federal agency are co-inventors, the small entity contractor, by virtue of an assignment from the contractor employee or the employee's current obligation to assign, would still have an undivided ownership interest in the joint invention. The undivided interest to the joint owner is provided at 35 U.S.C. 262. The requirement for an assignment or a currently existing obligation to assign is set forth in *Board of Trustees of Leland Stanford Junior University* v. *Roche Molecular Systems, Inc.*, 563 U.S. 776 (2011), where the

Court held: "[o]nly when an invention belongs to the contractor does the Bayh-Dole Act come into play." *Id.* at 790. In addition, " … unless there is an agreement to the contrary, an employer does not have rights in an invention 'which is the original conception of the employee alone.'" *Id.* at 786. Accordingly, when action is taken by the Federal agency under 35 U.S.C. 202(e)(1), the contractor could elect to retain full ownership rights. These ownership rights would be the same as those retained by a contractor under new paragraph (A) of section 1.27(a)(4)(ii), which applies when the subject invention was made solely by the small entity contractor employee(s). 35 U.S.C. 202(e) refers to this as "consolidating rights."

Consistent with the foregoing, this rule change clarifies that a use license under 35 U.S.C. 202(c)(4) resulting from a funding agreement with a Federal agency does not preclude claiming small entity status in the case of a Federal employee co-inventor when the Federal agency employing such co-inventor took action pursuant to 35 U.S.C. 202(e)(1), to exclusively license or assign whatever rights currently held or that it may acquire in the subject invention to the small business concern or nonprofit organization, subject to the license under 35 U.S.C. 202(c)(4). This is set forth in new paragraph (B) of section 1.27(a)(4)(ii). Of course, claiming small entity status in such a case would also require that no other interest in the invention is held by a party not qualifying as a small entity. Thus, new paragraph (B) clarifies, but does not change, the applicability of section 1.27(a)(4)(ii) in cases in which consolidation of rights to a small entity contractor has occurred under 35 U.S.C. 202(e)(1). This clarification is important, given that prior to this rulemaking, there may have been uncertainty as to whether the section 1.27(a)(4)(ii) exception could ever apply in cases in which there is a Federal employee co-inventor. Accordingly, notwithstanding the effective date of this rulemaking, for any small business concern or nonprofit organization contractor to which new paragraph (B) of section 1.27(a)(4)(ii) applies, the three-month time period under 37 CFR 1.28(a) for requesting a refund based on later establishment of small entity status is not affected by this rulemaking. This

accounts for the possibility that a small business concern or nonprofit organization contractor, to which paragraph (B) of section 1.27(a)(4)(ii) applies, might have paid full fees within three months prior to the effective date of this rulemaking based on a misunderstanding of the applicability of section 1.27(a)(4)(ii) as it existed prior to this rulemaking. In that event, the small business concern or nonprofit organization qualifying as a small entity, by virtue of paragraph (B) of section 1.27(a)(4)(ii), could take advantage of the provisions under 37 CFR 1.28(a) to obtain a refund based on later establishment of small entity status. A refund request under section 1.28(a) is really a request for a partial refund, since a section 1.28(a) refund is based on applying a discount subsequent to payment of the full fee.

Section 1.28(a) requires that the request for a refund of the excess amount, and an accompanying assertion of small entity status, be "filed within three months of the date of timely payment of the full fee." Except for the three-month window of opportunity provided by 37 CFR 1.28(a), the failure to establish status as a small entity in any application or patent prior to paying, or at the time of paying, any fee (1) precludes payment of the fee in the small entity amount, and (2) precludes a refund, pursuant to 37 CFR 1.26, of any portions of fees paid prior to establishing status as a small entity. Accordingly, any request for a refund under section 1.28(a) based on the clarifying effect of new paragraph (B) of section 1.27(a)(4)(ii) would only be appropriate if filed within three months of payment of the full fee, notwithstanding the effective date of this final rule. Because section 1.27(a)(4)(iii) sets forth a new government use license exception not available prior to the effective date of this rulemaking, a refund under section 1.28(a) for later establishment of small entity status on the basis of the new section 1.27(a)(4)(iii) exception could be obtained only for full patent fees that were timely paid on or after the effective date of this rulemaking and requested within three months of payment of the full fee.

Regarding new section 1.27(a)(4)(iii), which applies to government use licenses arising under a CRADA where the small entity retains all ownership rights, paragraph (B) covers situations in which the Federal laboratory took action under 15 U.S.C. 3710a(b)(3)(D), to waive in whole any right of ownership the Government may have to the subject invention made by the small business concern or nonprofit organization. Paragraph (A) of section 1.27(a)(4)(iii) applies to government use licenses arising in situations in which the invention to which title is retained, was made solely by the employee of the small business concern or nonprofit organization. Thus, consolidation of rights to a small entity collaborating party, under the CRADA provision of 15 U.S.C. 3710a(b)(3)(D), is treated similarly to the way in which consolidation of rights to a contractor, under the Bayh-Dole Act provision of 35 U.S.C. 202(e)(1), is treated under 37 CFR 1.27(a)(4)(ii). All the exceptions under 37 CFR 1.27(a)(4)(i) through (iii) require that the Government or the Federal agency receive no more than the applicable government use license and that there is no other interest in the invention held by a party not qualifying as a small entity.

New section 1.27(a)(4)(iv) is added to specify that regardless of whether a government use license exception applies, no refund under 37 CFR 1.28(a) is available for any patent fee paid by the Government.

When the exception at 37 CFR 1.27(a)(4) was originally promulgated, the basis for the exception, as it related to the obligatory license to the Federal government under 35 U.S.C. 202(c)(4), was "to avoid frustrating the intent of Pub. L. 97-247 and Pub. L. 96-517 when taken together." See Revision of Patent Practice, 49 FR 548, Jan. 4, 1984. (Public Law 97-247 was a 1982 appropriations act from which the small entity discount originated, and Public Law 96-517 is a reference to the Bayh-Dole Act of 1980.) No such basis exists for extending the government use license exceptions to the micro entity provisions. In addition, although the USPTO can provide for government use license exceptions for small entity status qualification, these

exceptions cannot apply for purposes of qualifying as a micro entity on the gross income basis. The reason for this is that the statute authorizing micro entity patent fee discounts—35 U.S.C. 123(a)(4)—disqualifies an entity from micro entity status if it has assigned, granted, or conveyed a license or other ownership interest in the invention to an entity that exceeded the gross income limit (currently $206,109) in its previous calendar year's gross income. Because a "gross national income" is attributed to the United States each year, any government use license runs afoul of the 35 U.S.C. 123(a)(4) qualification requirement. Accordingly, a government use license may not disqualify an applicant from a small entity status, but does disqualify the applicant from micro entity status. This applies to micro entity status on the "institution of higher education basis" under section 1.29(d) as well as micro entity status on the "gross income basis" under section 1.29(a). A clarifying amendment to 37 CFR 1.29 is made in order to explicitly reflect this.

Discussion of Regulatory Changes: These rule changes amend 37 CFR 1.27(a)(4) to clarify and expand the exceptions to the general rule that every party holding rights to an invention must qualify as a small entity under 37 CFR 1.27 in order for small entity status to be properly claimed.

A new introductory clause is added to 37 CFR 1.27(a)(4) to limit eligibility for each government use license exception to patent applications filed and prosecuted at no expense to the Government, with the exception of any expense taken to deliver the application and fees to the USPTO on behalf of the applicant. A new paragraph (a)(4)(iv) is added to 37 CFR 1.27 to specify that regardless of whether a government use license exception applies, no refund under 37 CFR 1.28(a) is available for any patent fee paid by the Government. To overcome any reluctance of research partners to take responsibility for seeking patent protection of federally supported inventions, the new section 1.27(a)(4) introductory clause, combined with new

paragraph (a)(4)(iv), should encourage small business concern and nonprofit organization contractors and collaborators to take the lead in seeking patent protection.

The regulations at 37 CFR 1.27(a)(4)(i) have long provided an exception for a government use license resulting from a rights determination under E.O. 10096, wherein title to the invention is retained by a Federal employee-inventor ("a person" as defined in 37 CFR 1.27(a)(1)). That exception is being amended to acknowledge the regulations contained in 37 CFR part 501, which implement E.O. 10096. This is done by making reference in the rule to 37 CFR 501.6, which substantially incorporates the E.O. 10096 criteria for the determination of rights in and to any invention made by a Government employee. This exception, as amended by this rulemaking, remains in section 1.27(a)(4)(i) under a new paragraph (A). A new paragraph (B) is added to section 1.27(a)(4)(i), referring to 15 U.S.C. 3710d(a), which provides for disposal of title to an invention from the Federal agency to the Federal employee-inventor, as well as the conditions under which the employee obtains or retains title to the invention, subject to a government use license. Accordingly, paragraphs 1.27(a)(4)(i)(A) and (B) both relate to the government use license exception in the context of Federal employee-inventors who retain title to their work inventions, subject to a government use license. Also added to section 1.27(a)(4)(i) is a new paragraph (C) for government use licenses to a Federal agency resulting from retention of rights by the inventor under 35 U.S.C. 202(d), when a small business concern or nonprofit organization contractor does not elect to retain title to an invention made by its employee under a Federal funding agreement. Provided the Federal agency receives no more than the government use license, and there is no other interest in the invention held by a party not qualifying as a small entity, the inventor who otherwise qualifies for small entity status is not prohibited from claiming small entity status as a result of retaining rights under 35 U.S.C. 202(d), to his or her invention. This exception is contingent upon the inventor meeting the conditions applicable under 37 CFR 401.9, to an employee/inventor of the small business firm or nonprofit

organization contractor not electing to retain title. (37 CFR part 401 implements the provisions of the Bayh-Dole Act codified in 35 U.S.C. 200-212.) Compared to what was proposed in the February 5, 2020, notice of proposed rulemaking (NPRM) at 85 FR 6476, the language of new paragraph 1.27(a)(4)(i)(C) is changed for clarity. For example, a specific reference to the 35 U.S.C. 202(c)(4) government use license was added, as well as the term "employee/inventor," which is the term 37 CFR 401.9 uses to refer to the contractor's employee. No new requirement is added to paragraph 1.27(a)(4)(i)(C) compared to the proposed requirements. Thus, section 1.27(a)(4)(i) continues to apply to small entity "persons," as defined in 37 CFR 1.27(a)(1), and as amended by this rulemaking, sets forth three types of government use licenses that would not disqualify a patent applicant from claiming small entity status for purposes of paying reduced patent fees.

With respect to "small business concerns" and "nonprofit organizations," as defined in 37 CFR 1.27(a)(2) and (3), there are generally two types of agreements into which they enter with the Federal Government that are pertinent to this rulemaking: (1) Federal funding agreements under the Bayh-Dole Act (as defined in 35 U.S.C. 201(b)), and (2) CRADAs, as provided for in 15 U.S.C. 3710a. Both of these agreements require a government use license to be granted to the Federal Government by the entity or person retaining title to an invention made under such agreement. The regulations at section 1.27(a)(4)(ii) continue to provide an exception for Bayh-Dole Act government use licenses under 35 U.S.C. 202(c)(4). To clarify that exception, new paragraphs (A) and (B) are added to section 1.27(a)(4)(ii). Paragraph 1.27(a)(4)(ii)(A) applies to the situation in which the invention under a Federal funding agreement was made solely by employees of the small business concern or nonprofit organization. Paragraph 1.27(a)(4)(ii)(B) addresses situations in which there is a Federal employee co-inventor.

Prior to this rulemaking, the patent rules did not provide any exception for use licenses reserved to the Government under a CRADA. The rule change provides an additional exception, in a new section 1.27(a)(4)(iii), for government use licenses for inventions made by small entities under a CRADA in situations under 15 U.S.C. 3710a(b)(2) and 3710a(b)(3)(D), wherein the small entity retains title to the invention.

Section 1.29 is amended to clarify that the government use license exceptions under 37 CFR 1.27(a)(4) do not apply for purposes of micro entity status qualification. The baseline small entity requirement under sections 1.29(a)(1) and (d)(1) cannot be met if qualification as a small entity under 37 CFR 1.27 depends on one of the government use license exceptions specified in 37 CFR 1.27(a)(4).

Response to Comments

The USPTO published a notice proposing changes to the rules of practice in patent cases to clarify and expand exceptions to the rule pertaining to government use licenses and their effect on small entity status for purposes of paying reduced patent fees, so as to support independent inventors, small business concerns, and nonprofit organizations in filing patent applications. *See* Small Entity Government Use License Exception, 85 FR 6476 (February 5, 2020). In response, the Office received two comments, one from a nonprofit association and one from an attorney, both of which fully endorsed the purpose and the content of the proposed changes. The Office thanks these commenters for their feedback.

Rulemaking Considerations

A. Administrative Procedure Act: The changes in this rulemaking involve rules of agency practice and procedure, and/or interpretive rules. *See Perez* v. *Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1204 (2015) (Interpretive rules "advise the public of the agency's construction of the statutes and rules

which it administers." (citation and internal quotation marks omitted)); *Nat'l Org. of Veterans' Advocates* v. *Sec'y of Veterans Affairs*, 260 F.3d 1365, 1375 (Fed. Cir. 2001) (Rule that clarifies interpretation of a statute is interpretive.); *Bachow Commc'ns Inc.* v. *FCC*, 237 F.3d 683, 690 (D.C. Cir. 2001) (Rules governing an application process are procedural under the Administrative Procedure Act.); *Inova Alexandria Hosp.* v. *Shalala*, 244 F.3d 342, 350 (4th Cir. 2001) (Rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims.).

Accordingly, prior notice and opportunity for public comment for the changes in this rulemaking are not required pursuant to 5 U.S.C. 553(b) or (c), or any other law. *See Perez*, 135 S. Ct. at 1206 (Notice and comment procedures are required neither when an agency "issue[s] an initial interpretive rule" nor "when it amends or repeals that interpretive rule."); *Cooper Techs. Co.* v. *Dudas*, 536 F.3d 1330, 1336-37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice and comment rulemaking for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice" (quoting 5 U.S.C. 553(b)(A))). However, the Office chose to seek public comment before implementing the rule to benefit from the public's input.

B. Regulatory Flexibility Act: Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), whenever an agency is required by 5 U.S.C. 553 (or any other law) to publish an NPRM, the agency must prepare and make available for public comment an Initial Regulatory Flexibility Analysis, unless the agency certifies under 5 U.S.C. 605(b) that the proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 603, 605. The Senior Counsel for Regulatory and Legislative Affairs in the Office of General Law of the USPTO certified to the Chief Counsel for Advocacy of the Small Business Administration that the NPRM will not have a significant economic impact on a

substantial number of small entities. See 5 U.S.C. 605(b). For the reasons set forth herein, the Senior Counsel for Regulatory and Legislative Affairs in the Office of General Law of the USPTO has certified to the Chief Counsel for Advocacy of the Small Business Administration that this final rule will not have a significant economic impact on a substantial number of small entities.

The USPTO is amending the rules of practice in patent cases to clarify and expand exceptions to the rule pertaining to government use licenses and their effect on small entity status for purposes of paying reduced patent fees, so as to support independent inventors, small business concerns, and nonprofit organizations in filing patent applications. To be entitled to pay small entity patent fees, all parties holding rights in the invention must qualify for small entity status. Prior to this rulemaking, there were two exceptions to this rule, both of which continue to apply, as clarified and expanded by this rulemaking. Both these exceptions relate to government use licenses granted under the law by independent inventors, small business concerns, or nonprofit organizations otherwise qualifying as a small entity, where such entities retain title to their inventions. The first exception applies when an inventor employed by the Federal Government has an obligation to grant the government use license in the workplace invention in which the inventor obtains title pursuant to a rights determination under E.O. 10096. This exception continues to apply and is amended to clarify that it applies to employees of Federal laboratories under 15 U.S.C. 3710d(a). The second exception applies when the government use license in the Government-funded invention is an obligation (pursuant to 35 U.S.C. 202(c)(4)) under a funding agreement with a Federal agency. This exception is expanded to cover the situations in which a small business concern or nonprofit organization qualifying as a small entity does not elect to retain title to an invention made by its employee under a Federal funding agreement, and the Federal agency allows the inventor to retain title to the federally funded invention. In that case, a government use license (equivalent to that specified in 35 U.S.C. 202(c)(4)) is an obligation

arising from the employee's retention of rights under 35 U.S.C. 202(d). The second exception is also expanded to address situations in which there is a Federal employee co-inventor. Further, this rulemaking adds a third exception to cover a government use license arising from an obligation under a CRADA with a Federal agency pursuant to 15 U.S.C. 3710a(b). Regardless of whether any of the aforementioned exceptions apply, no refund is available for any patent fee paid by the Government. In addition, patent applications filed and prosecuted at Government expense will not be entitled to the small entity discount. Finally, the qualifications for the micro entity patent fee discount are clarified.

The rule changes are designed to encourage persons, small businesses, and nonprofit organizations to collaborate with the Federal Government by providing an opportunity to qualify for the small entity patent fees discount for inventions made during the course of federally funded or federally supported research. Thus, this rule allows more entities to qualify for the small entity fee discount; these entities may qualify for a 50% reduction in fees, resulting in a substantial cost savings to them. Although the cost savings may be substantial, this rule is not expected to impact a large number of small entities. We estimate the number of small entities impacted by this rule to be in the range of 750 to 1,000, based on the number of active CRADAs reported for FY 2015 and its projected growth.

These changes are procedural and are not expected to have a direct economic impact on small entities. For the reasons described above, this rule is not expected to have a significant economic impact on a substantial number of small entities.

C. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The Office has complied with Executive Order 13563 (Jan. 18, 2011). Specifically, the Office has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across Government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs): This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866 (Jan. 30, 2017).

F. Executive Order 13132 (Federalism): This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

G. Executive Order 13175 (Tribal Consultation): This rulemaking will not: (1) Have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

H. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

I. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

J. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

K. Executive Order 12630 (Taking of Private Property): This rulemaking will not affect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

L. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), prior to issuing any final rule, the USPTO will submit a report containing the rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this rulemaking are not expected to result in an annual effect on the economy of $100 million or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with

foreign-based enterprises in domestic and export markets. Therefore, this rulemaking is not a "major rule" as defined in 5 U.S.C. 804(2).

M. Unfunded Mandates Reform Act of 1995: The changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of $100 million (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of $100 million (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 et seq.

N. National Environmental Policy Act of 1969: This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. *See* 42 U.S.C. 4321 et seq.

O. National Technology Transfer and Advancement Act of 1995: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions that involve the use of technical standards.

P. Paperwork Reduction Act of 1995: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. This rulemaking does not involve any new information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information has a valid OMB control number.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Biologics, Courts, Freedom of information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

For the reasons stated in the preamble, 37 CFR part 1 is amended as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), unless otherwise noted.

2. Section 1.27 is amended by revising paragraph (a)(4) to read as follows:

§ 1.27 Definition of small entities and establishing status as a small entity to permit payment of small entity fees; when a determination of entitlement to small entity status and notification of loss of entitlement to small entity status are required; fraud on the Office.

(a) * * *

(4) *Federal Government Use License Exceptions*. In a patent application filed, prosecuted, and if patented, maintained at no expense to the Government, with the

exception of any expense taken to deliver the application and fees to the Office on behalf of the applicant:

(i) For persons under paragraph (a)(1) of this section, claiming small entity status is not prohibited by:

(A) A use license to the Government resulting from a rights determination under Executive Order 10096 made in accordance with § 501.6 of this title;

(B) A use license to the Government resulting from Federal agency action pursuant to 15 U.S.C. 3710d(a) allowing the Federal employee-inventor to obtain or retain title to the invention; or

(C) A use license to a Federal agency resulting from retention of rights under 35 U.S.C. 202(d) by an inventor employed by a small business concern or nonprofit organization contractor, provided the license is equivalent to the license under 35 U.S.C. 202(c)(4) the Federal agency would have received had the contractor elected to retain title, and all the conditions applicable under § 401.9 of this title to an employee/inventor are met.

(ii) For small business concerns and nonprofit organizations under paragraphs (a)(2) and (3) of this section, a use license to a Federal agency resulting from a funding agreement with that agency pursuant to 35 U.S.C. 202(c)(4) does not preclude claiming small entity status, provided that:

(A) The subject invention was made solely by employees of the small business concern or nonprofit organization; or

(B) In the case of a Federal employee co-inventor, the Federal agency employing such co-inventor took action pursuant to 35 U.S.C.

202(e)(1) to exclusively license or assign whatever rights currently held or that it may acquire in the subject invention to the small business concern or nonprofit organization, subject to the license under 35 U.S.C. 202(c)(4).

(iii) For small business concerns and nonprofit organizations under paragraphs (a)(2) and (3) of this section that have collaborated with a Federal agency laboratory pursuant to a cooperative research and development agreement (CRADA) under 15 U.S.C. 3710a(a)(1), claiming small entity status is not prohibited by a use license to the Government pursuant to:

(A) 15 U.S.C. 3710a(b)(2) that results from retaining title to an invention made solely by the employee of the small business concern or nonprofit organization; or

(B) 15 U.S.C. 3710a(b)(3)(D), provided the laboratory has waived in whole any right of ownership the Government may have to the subject invention made by the small business concern or nonprofit organization, or has exclusively licensed whatever ownership rights the Government may acquire in the subject invention to the small business concern or nonprofit organization.

(iv) Regardless of whether an exception under this paragraph (a)(4) applies, no refund under § 1.28(a) is available for any patent fee paid by the Government.

* * * * *

3. Section 1.29 is amended by revising paragraphs (a)(1) and (d)(1) to read as follows:

§ 1.29 Micro entity status.

(a) * * *

(1) The applicant qualifies as a small entity as defined in § 1.27 without relying on a government use license exception under § 1.27(a)(4);

* * * * *

(d) * * *

(1) The applicant qualifies as a small entity as defined in § 1.27 without relying on a government use license exception under § 1.27(a)(4); and

* * * * *

Andrei Iancu,
Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.
[FR Doc. 2020-27049 Filed: 12/18/2020 8:45 am; Publication Date: 12/21/2020]